

**REMARKS**

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks and pursuant to 37 C.F.R. § 1.112, are respectfully requested.

By the present amendment, claims 8 and 13 have been canceled, without prejudice or disclaimer to the subject matter disclosed therein. Claims 7 and 12 have been amended to incorporate the subject matter of canceled claims 8 and 13, respectively. Claim 1 has been amended to recite that the extract of green tee contains from 20% to 50% by mass of catechols (which is what was claimed by claim 1 prior to the last amendment) and to incorporate the subject matter of original claim 3. Claim 3 has been amended to recite that the composition of claim 1 contains from 20% to 30% by mass of catechols. Support for this amendment to claim 3 may be found, at the very least, in claim 2 as originally filed. Claim 6 has been amended to recite a “method for the curative and prophylactic treatment of obesity in a patient”. Support for this amendment to claim 6 may be found, at the very least, on page 4, lines 9-25. Claim 11 has been amended to recite “A method for promoting weight loss or maintaining a desired weight level”. Support for this amendment to claim 11 may be found, at the very least, on page 4, lines 19-25, of the specification as filed. Support for new claim 21 may be found, at the very least, in claims 1 and 3 as originally filed and on page 9, lines 27-29, of the specification as filed. Support for new claim 22 may be found, at the very least, in claim 6 as originally filed; on page 4, lines 9-25, of the specification as originally filed; and on page 9, lines 27-29, of the specification as filed. Support for new claim 23 may be found, at the very least, in claim 11 as

originally filed; on page 4, lines 19-25, of the specification as filed; and on page 9, lines 27-29, of the specification as filed. No new matter has been added by the present amendment.

**Rejection of Claims 1, 4 and 11-15 Under 35 U.S.C. § 112, Second Paragraph**

Claims 1, 4 and 11-15 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Claim 1 is purportedly indefinite for being unclear as to whether the extract contains 20-30% catechols, or the composition as a whole contains 20-30% catechols. Claim 1 has been amended to make clear that the extract contains 20-50% by mass of catechols, thereby rendering its rejection moot.

Claim 6 is purportedly indefinite for omitting essential steps from the method claimed. Claim 6 has been amended to recite a method for treatment of obesity which comprises administering to a patient an extract or powder of green tea, thereby including all essential steps and rendering its rejection moot.

Claims 11-15 are purportedly indefinite for reciting the term “esthetic” which is purportedly vague and for reciting “catechol-enriched” which is also purportedly vague. Claims 11-15 have been amended to recite that the method is for promoting weight loss or maintaining a desired weight level in a human being, and that the extract comprises catechol, thereby removing the purportedly vague terms and rendering this rejection moot.

Finally, claim 4 is purportedly vague for lacking antecedent basis for the phrase “the concentration of caffeine.” Claim 1 has been amended to recite that the extract contains from 5% to 10% by mass of caffeine, thereby providing proper antecedent basis for “caffeine” in claim 4, and rendering this rejection moot.

In light of the above, applicants respectfully request withdrawal of these rejections under 35 U.S.C. § 112, second paragraph.

**Rejection of Claims 1 and 3-21 Under 35 U.S.C. § 103(a)**

Claims 1 and 3-21 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Kimura et al (U.S. Patent No. 5,776,756). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Kimura et al is drawn to hypertensive agents comprising a fermentation liquid. The fermentation liquid is obtained by inoculating *Bacillus natto* or hay or grass bacilli in a medium containing rice brans, soybeans, sources of carbon and water, cultivating the bacilli and filtering the resulting broth and optionally an extract of green tea.

The present invention is drawn to a composition for the curative and prophylactic treatment of obesity comprising an extract of green tea containing from 20% to 50% by mass of catechols (expressed as epigallocatechol gallate (EGCG)) and from 5% to 10% by mass of caffeine. The present invention is also drawn to methods of preparing such compositions, and methods of using such compositions for the curative and prophylactic treatment of obesity in a patient.

Kimura et al does not disclose or suggest each of the aspects of the present invention. Initially, there are many different varieties and botanical types of tea plants (e.g. Assamica, Macrophylla, Yunnan, Guangdong, Viridis, Sinensis), with variable compositions. Therefore, according to the type of tea plant used as a starting compound, the caffeine content and the catechine content of the plant may markedly vary. Dried extract contents of different botanical types of tea plants, prepared with 80% ethanol, are shown in Table 1.

**Table 1**

Type of Tea Plant	Caffeine (%)	Catechines (%)
Assamica Type	6.0%	24.4%
Chakra Type	7.0%	17.5%
Mandiri Type	4.6%	14.7%
Gunung Type	5.7%	6.5%
Sidamanik Type	5.3%	3.0%

Furthermore, according to the nature of the hydro-alcoholic mixture, the polarity of the solvent used for extraction is variable. Therefore, the ability to solve green tea constituents may vary along with the solvent used, and the constituent proportions of the extracted product may also vary with the extraction solvent used. See Table 2, which lists the dried extract contents obtained from Assamica type of tea plant.

**Table 2**

Alcohol content	Caffeine (%)	Catechines (%)
100 % Ethanol	8.35%	22.0 %
80 % Ethanol	6.0%	24.4 %
70 % Ethanol	5.5%	19.7 %
50 % Ethanol	5.1%	18.3 %
30 % Ethanol	4.8%	17.9 %
50 % Methanol	5.7%	20.0 %

Kimura et al does not recognize the advantages of using a particular type of green tea plant together with a specific method of obtaining an extract (i.e. using a specific alcohol content for the extraction solvent). The present inventors recognized these advantages, and developed a method wherein the produced extract contains 20% to 50% by mass of catechols (expressed as epigallocatechol gallate (EGCG) and from 5% to 10% by mass of caffeine. Such an extract has been shown by the present inventors to be useful for the treatment of obesity. Kimura et al does not even specify the type of plant to be used as a starting material, nor does it disclose the percent of alcohol used in the extraction solvent. Therefore, Kimura et al does not disclose or suggest the characteristics of the tea extract used in the present invention, which comprises from 20% to 50% by mass of catechols expressed as epigallocatechol gallate and from 5% to 10% by mass of caffeine.

Furthermore, Kimura et al does not disclose or suggest the composition of claim 21, the method of manufacturing of claim 22, or the method of use of claim 23. Each of these claims require that the catechols and caffeine in the green tea extract be present in a

ratio of EGCG/caffeine of between 2 and 10. As discussed on page 9, lines 14-29, this ratio of EGCG/caffeine was found to be advantageous. In accordance with MPEP 2144.05, applicants can rebut a *prima facie* case of obviousness based on overlapping ranges by showing the criticality of the claimed range. Since Kimura et al does not disclose or suggest the advantages of using a green tea extract which has a ratio of EGCG/caffeine of between 2 and 10, Kimura et al does not disclose or suggest the invention of claims 21-23.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

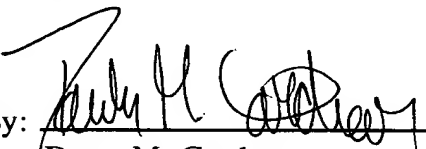
#### **CONCLUSION**

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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**Attachment to Amendment and Reply dated April 2, 2002**

**Marked-up Claims 1, 3, 6, 7, 11 and 12**

1. (Three Times Amended) A composition for the curative and prophylactic treatment of obesity, comprising an extract of green tea [containing] wherein said extract contains from 20% to [30] 50% by mass of catechols expressed as epigallocatechol gallate (EGCG), and from 5% to 10% by mass of caffeine.

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3. (Twice Amended) A composition according to Claim 1, wherein the extract of green tea contains from 20% to 30% by mass of catechols expressed as epigallocatechol gallate (EGCG) [5% to 10% by mass of caffeine].

6. (Three Times Amended) A method [of manufacturing a medicinal product which has antilipase and/or thermogenic properties, and which is intended] for the curative and prophylactic treatment of obesity[, comprising obtaining] in a patient which comprises administering to the patient an extract or powder of green tea [by extraction of green tea].

7. (Twice Amended) A method according to Claim 6, wherein the extract of green tea contains from 20% to 50% by mass of catechols expressed as epigallocatechol gallate (EGCG), and from 5% to 10% by mass of caffeine.

11. (Three Times Amended) A method for [the esthetic treatment of] promoting weight loss or maintaining a desired weight level in a human being, wherein said method



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**Marked-up Claims 1, 3, 6, 7, 11 and 12**

comprises the oral administration of a [catechol-enriched extract of] green tea extract comprising catechol in order to bring about a loss of weight or to maintain a desired weight level.

12. (Three Times Amended) A method according to Claim 11, wherein said oral administration comprises administration of a extract of green tea containing from 20% to 50% by mass of catechols expressed as epigallocatechol gallate (EGCG), and from 5% to 10% by mass of caffeine.